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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/661,920 | 09/14/2000 | Wilson Moya | MCA-474 | 9899 |

25182 7590 05/14/2003
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| EXAMINER |
| VO, HAI |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1771 | 11 |

DATE MAILED: 05/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/661,920 | MOYA, WILSON |
| | Examiner Hai Vo | Art Unit 1771 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 31 March 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 2-4, 9 and 11-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 13 is/are allowed.

6) Claim(s) 2-4, 9, 11, 12 and 14-24 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
2. Claims 2, 3, 9, 11, 12, 14-16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 2 233 626. Figures 1-3 of FR'626 meet every limitation of the claims. FR'626 discloses an absorbent surface structure comprising a flat support **1** and a layer of porous PVC fibers bonded to the support **1** (figure 1, page 3). The absorbent surface structure comprises of a plurality of pads **5X** wherein each pad is separated from each other by a non-porous lane **3**. The lane **3** is designed to prevent cross-talk by diffusion from one pad to another. Figure 2 of FR'626 shows that a sampling instrument comprising a plate **12** that has several teeth **14** whose terminal surface **14A** is porous (pages 6 and 7). Each tooth **14** rests on each corresponding pad **5X**. It is the examiner's position that FR'626 anticipated the claimed subject matter.
3. Claims 2-4, 9, 11, 12 and 14-24 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 272 043. EP'043 discloses a diagnostic test device comprising a well **7** comprising a porous reaction layer **13**, a porous sealing layer **15**, a barrier layer **17**, and a liquophobic zone **21** provided at the periphery of each well to prevent lateral flow from one well to another (figures 2 and 3, column 6, line 32 and column 9, lines17-29). It is the examiner's position that the liquophobic zone

would be inherently a non-porous region so as to satisfy its functions such as to prevent lateral flow from one well to another. In view of the interpretation, the well 7 is comprised of two layers of a porous structure having one area of porous material **13, 15**, and one area of non-porous material **21**. EP'043 discloses the composite membrane being made of polyamide (column 6, line 49). EP'043 discloses the surface modifying polymer being used to prepare the composite membrane with controlled surface properties (column 7, lines 16-26). EP'043 discloses the reaction layer being treated with suitable reagents at the time at which diagnostic tests are to be performed. It is the examiner's position that EP'043 anticipated the claimed subject matter.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over FR 2 233 626. FR'626 discloses the surface zone **5** formed in a shape of rectangular or square section (page 5). *In re Dailey*, 149 USPQ 47 (CCPA 1976), there is nothing on the record that convinces the examiner that the particular shape of the surface zone of the porous material is significant or is anything more than one of numerous shapes a person of ordinary skill in the art would find obvious for the

purpose of providing the shape of the surface zone of the porous material, therefore, the shape of the surface zone of the porous material in itself would not render the claims patentable over FR'626. See *Graham v. John Deere Co.*,

Allowable Subject Matter

6. Claim 13 is allowed. Reasons for allowance have been indicated in Paper no. 6.

Response to Arguments

7. The specification and abstract objections in Paper no. 6 have been overcome by the present amendment and response.
8. The art rejections over FR 233 626 are maintained because of the following reasons. The arguments that FR'626 does not teach forming a porous structure and then selectively rendering certain portions non-porous as the present invention but rather starts with a non-porous base layer and then adds certain areas on top of it that are porous strands are directed to process limitations. The arguments are not commensurate in scope with the present product claims. Nothing about the process has been included in the claims. The art rejections over FR'626 are thus sustained.
9. The art rejections over EP 272 043 are maintained because of the following reasons. Applicant argues that EP'043 does not teach or suggest a membrane including a structure in one layer that has porous and non-porous regions in it. This is not found persuasive. The composite membrane of EP'043 does meet all the limitations of structure as set forth in the claims. The composite membrane comprises a reaction layer 13, a sealing layer 15, a barrier layer 17 and a

liquophobic zone 21 provided at the periphery of each well (figures 1 and 3). The examiner interprets that the composite membrane having the porous areas 13, 15 surrounded by a non-porous liquophobic zone 21. Again, the examiner maintains that the liquophobic zone 21 has to be non-porous to satisfy its function, i.e., to eliminate lateral flow from one well to another.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (703) 605-4426. The examiner can normally be reached on Tue-Fri, 8:30-6:00 and on alternating Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (703) 308-2414. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

HV
May 5, 2003



TERREL MORRIS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700